NEWSLETTER: News from the HTA Agencies

May 2022

SUMMARY

Agency	N° of drugs	Drug Name
CADTH	4	Alpha1-proteinase inhibitor (Human) · Prasterone · Ripretinib · Selpercatinib
HAS	14	[18F]PSMA-1007 · Amivantamab · Bimékizumab · Degarelix · Évolocumab · Inebilizumab · **Mépolizumab** · Osimertinib · **Pembrolizumab** · Roxadustat · **Sofosbuvir/Velpatasvir** · Sofosbuvir/Voxilaprévir/Velpatasvir · **Sotorasib** · Tofacitinib
ICER	0	-
IQWIG	30	Avacopan · Burosumab · Calcifediol · Duvelisib · Ertugliflozin · **Filgotinib** · Isoflurane · Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] · **Mepolizumab** · **Nivolumab** · Ozanimod · **Pembrolizumab** · Sacituzumab · **Sofosbuvir/velpatasvir** · **Sotorasib**
NICE	3	Avelumab · Romosozumab · Tepotinib
SMC	12	Cemiplimab · Dapagliflozin · Daratumumab · **Filgotinib** · Liraglutide · **Mepolizumab** · **Nivolumab** · Oritavancin · **Pembrolizumab** · Venetoclax

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CADTH Evidence Driven.

https://www.cadth.ca/

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Info on costs
Alpha1-proteinase inhibitor (Human)	Zemaira	Maintenance treatment in adults with severe alpha1-proteinase inhibitor deficiency (e.g., genotypes PiZZ, PiZ(null), Pi(null,null), or PiSZ) and clinical evidence of emphysema	CADTH Reimbursement recommendation 02/05/2022	https://www.cadth.ca/sites/default/files/DRR/2022/ST0702%20Zemaira%20-%20CADTH%20Final%20Rec%20Final.pdf	The CADTH Canadian Plasma Protein Product Expert Committee (CPEC) recommends that A1-PI (human) (Zemaira) be reimbursed for maintenance treatment in adults with severe A1-PI deficiency (e.g., genotypes PiZZ, PiZ(null), Pi(null,null), PiSZ) and clinical evidence of emphysema only if the conditions listed are met: ●Zemaira should be reimbursed in adults with severe A1-PI deficiency (e.g., genotypes PiZZ, PiZ(null), Pi(null,null), PiSZ) and clinical evidence of emphysema ● Patients must be nonsmokers for at least 6 months	Treatment with Zemaira is expected to cost approximately $101,748 per patient annually.
Prasterone	Intrarosa	Treatment of postmenopausal vulvovaginal atrophy	CADTH Reimbursement recommendation 03/05/2022	https://www.cadth.ca/sites/default/files/DRR/2022/SR0707%20Intrarosa%20-%20CADTH%20Final%20Rec-meta.pdf	CADTH recommends that Intrarosa should be reimbursed by public drug plans for the treatment of postmenopausal vulvovaginal atrophy (VVA) if certain conditions are met: ● Reimburse in a similar manner as currently funded vaginal estrogen products. ●Prasterone should be negotiated so that its price does not exceed the least costly vaginal estrogen product reimbursed for the treatment of postmenopausal VVA.	Treatment with Intrarosa is expected to cost approximately $532 per patient per year
Ripretinib	Qinlock	Treatment of adult patients with advanced gastrointestinal stromal tumour who have received prior treatment with imatinib, sunitinib, and regorafenib	CADTH Reimbursement recommendation 16/05/2022	https://www.cadth.ca/sites/default/files/DRR/2022/PC0265%20Qinlock%20-%20Confidential%20Final%20CADTH%20Rec-meta.pdf	CADTH recommends that Qinlock be reimbursed by public drug plans for the treatment of adult patients with advanced gastrointestinal stromal tumour (GIST) if certain conditions are met: 1.Treatment with ripretinib should only be reimbursed when initiated in adults (≥ 18 years) with GIST who meet all of the following: 1. progression on or intolerance to imatinib, sunitinib, and regorafenib 2. adequate hematological and organ function. 2. Patients should have good PS. 3. Patients must not have any of the following: 1. active central nervous system metastases 2.clinically significant cardiac conditions or other comorbidities 3.gastrointestinal problems preventing the ingestion or absorption of oral medications	Treatment with Qinlock is expected to cost approximately $18,171 per patient per 28 days

CADTH Evidence Driven.

https://www.cadth.ca/

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Selpercatinib	Retevmo	As monotherapy for the treatment of metastatic RET fusion-positive non-small cell lung cancer in adult patients	CADTH Reimbursement recommendation 18/05/2022	https://www.cadth.ca/sites/default/files/DRR/2022/PC0261%20Retevmo%20-%20CADTH%20Final%20Rec-meta.pdf	CADTH recommends that Retevmo be reimbursed by public drug plans for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non–small cell lung cancer (NSCLC), if certain conditions are met: 1.Treatment with selpercatinib should be reimbursed when initiated in adult (≥ 18 years) patients with metastatic RET fusion-positive NSCLC who meet one of the following criteria: 1. for first-line treatment 2. after prior systemic therapy 2. Patient must have: 1. good performance status 2.clinically stable CNS disease or no brain metastases.	Treatment with Retevmo is estimated to cost $11,172 to $14,896 per 28 days if given 120 mg to 160 mg orally twice daily depending on whether the patient's weight exceeds 50 kg.

https://www.has-sante.fr/

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[18F]PSMA-1007	Radelumin	RADELUMIN est destiné à la tomographie par émission de positons (TEP).	Avis de la CT 04/05/2022	https://www.has-sante.fr/jcms/p_3337433/fr/radelumin-18f-psma-1007-cancer-de-la-prostate	**Autorisation d'accès précoce** octroyée à la spécialité RADELUMIN ([18F]PSMA-1007) dans l'indication « Ce médicament est à usage diagnostique uniquement. RADELUMIN est destiné à la tomographie par émission de positons (TEP). La TEP après injection de RADELUMIN est indiquée chez un patient en récidive biologique d'un cancer de la prostate, traité initialement de façon radicale, avec réaugmentation de la concentra-tion sérique d'antigène spécifique de la prostate (PSA).
Amivantamab	Rybrevant	En monothérapie dans le traitement des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) avancé avec mutations activatrices du récepteur du facteur de croissance épidermique (EGFR) par insertion dans l'exon 20, après échec d'un traitement à base de sels de platine et en situation de dernier recours	Avis de la CT 02/05/2022	https://www.has-sante.fr/jcms/p_3336657/fr/rybrevant-amivantamab	**Autorisation d'accès précoce** octroyée à la spécialité RYBREVANT dans l'indication « En monothérapie dans le traitement des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) avancé avec mutations activatrices du récepteur du facteur de croissance épidermique (EGFR) par insertion dans l'exon 20, après échec d'un traitement à base de sels de platine et en situation de dernier recours
Bimékizumab	Bimzelx	Traitement du psoriasis en plaques sévère de l'adulte qui nécessite un traitement systémique, en impasse thérapeutique et présentant un retentissement psychosocial important. Impasse thérapeutique : en cas de contre-indication, d'intolérance ou d'échec à tous les mécanismes d'action des traitements systémiques non biologiques et biologiques (antiTNFα, anti-IL17, anti-IL23 et anti-IL12 & 23).	Avis de la CT 02/05/2022	https://www.has-sante.fr/jcms/p_3336645/fr/bimzelx-bimekizumab	**Autorisation d'accès précoce refusée** à la spécialité BIMZELX dans l'indication « Traitement du psoriasis en plaques sévère de l'adulte qui nécessite un traitement systémique, en impasse thérapeutique et présentant un retentissement psychosocial important. Impasse thérapeutique : en cas de contre-indication, d'intolérance ou d'échec à tous les mécanismes d'action des traitements systémiques non biologiques et biologiques (antiTNFα, anti-IL17, anti-IL23 et anti-IL 12 & 23).

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Degarelix	Firmagon	Traitement du cancer de la prostate hormono-dépendant localisé à haut risque ou localement avancé en association avec une radiothérapie. - Traitement néoadjuvant à une radiothérapie chez les patients présentant un cancer de la prostate hormono-dépendant localisé à haut risque ou localement avancé.	Avis de la CT 20/05/2022	https://www.has-sante.fr/jcms/p_3338772/fr/firmagon-degarelix-cancer-de-la-prostate	**Nouvelles indications.** Avis favorable au remboursement dans le : ● Traitement du cancer de la prostate hormono-dépendant localisé à haut risque ou localement avancé en association avec une radiothérapie. ●Traitement néoadjuvant à une radiothérapie chez les patients présentant un cancer de la prostate hormono-dépendant localisé à haut risque ou localement avancé. la Commission considère que FIRMAGON (dégarélix) n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la prise en charge du cancer de la prostate hormonodépendant localisé à haut risque ou localement avancé, en néoadjuvant à une radiothérapie ou en association avec la radiothérapie.
Évolocumab	Repatha	●Hypercholestérolémie et dyslipidémie mixte ●Hypercholestérolémie familiale	Avis de la CT 17/05/2022	https://www.has-sante.fr/jcms/p_3338762/fr/repatha-evolocumab-hypercholesterolemie-familiale-heterozygote-hfhe	**Nouvelles indications** ●Avis favorable au remboursement chez les enfants et adolescents à partir de 10 ans présentant une hypercholestérolémie familiale hétérozygote (HFHe), insuffisamment contrôlée (LDL-c > 1,30 g/L) par un traitement oral maximal toléré, en complément d'un régime alimentaire, et : - en association à un traitement hypolipémiant optimisé ; -en monothérapie en cas de contre-indication ou d'intolérance avérée à la fois aux statines et à l'ézétimibe. ●Avis favorable au remboursement chez les enfants et adolescents âgés de 10 et 11 ans, présentant une hypercholestérolémie familiale homozygote (HFHo) en association avec d'autres thérapies hypolipémiantes. Avis défavorable au remboursement dans les autres situations cliniques de l'AMM, notamment en cas de traitement hypolipémiant non optimisé. REPATHA (evolocumab) apporte une amélioration du service médical rendu mineure (ASMR IV) à la prise en charge des enfants de 10 ans à 11 ans présentant une hypercholestérolémie familiale homozygote, en association avec d'autres thérapies hypolipémiantes

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Inebilizumab	Uplizna	en monothérapie dans le traitement des troubles du spectre de la neuromyélite optique (TSNMO) chez les patients adultes qui sont séropositifs pour les immunoglobulines G antiaquaporine-4 (AQP4-IgG	Avis de la CT 30/05/2022	https://www.has-sante.fr/jcms/p_3341895/fr/uplizna-inebilizumab-maladies-du-spectre-de-la-neuromyelite-optique-nmosd	**Autorisation d'accès précoce** octroyée à la spécialité UPLIZNA (inebilizumab) dans l'indication « en monothérapie dans le traitement des troubles du spectre de la neuromyélite optique (TSNMO) chez les patients adultes qui sont séropositifs pour les immunoglobulines G antiaquaporine-4 (AQP4-IgG »
Mépolizumab	Nucala	syndrome hyperéosinophilique lymphoïde ou idiopathique insuffisamment contrôlé.	Avis de la CT 30/05/2022	https://www.has-sante.fr/jcms/p_3341449/fr/nucala-mepolizumab-syndrome-hypereosinophilique	**Nouvelle indication.** Avis favorable au remboursement en traitement additionnel, chez les patients adultes qui présentent un syndrome hyperéosinophilique lymphoïde ou idiopathique insuffisamment contrôlé. Avis défavorable au remboursement dans les autres situations de l'AMM. NUCALA (mépolizumab) apporte une amélioration du service médical rendu mineure (ASMR IV) dans la stratégie de prise en charge du syndrome hyperéosinophilique lymphoïde ou idiopathique insuffisamment contrôlé.
Osimertinib	Tagrisso	traitement adjuvant après résection tumorale complète et après chimiothérapie adjuvante si indiquée des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) de stade IB – IIIA avec mutations activatrices du récepteur du facteur de croissance épidermique (EGFR) par délétion de l'exon 19 ou substitution de l'exon 21 (L858R).	Avis de la CT 30/05/2022	https://www.has-sante.fr/jcms/p_3313529/fr/tagrisso-osimertinib-cancer-bronchique-non-a-petites-cellules-cbnpc	**Nouvelle indication.** Avis favorable au remboursement uniquement dans le traitement adjuvant après résection tumorale complète et après chimiothérapie adjuvante si indiquée des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) de stade IB – IIIA avec mutations activatrices du récepteur du facteur de croissance épidermique (EGFR) par délétion de l'exon 19 ou substitution de l'exon 21 (L858R). Avis défavorable au remboursement dans les autres situations adjuvantes. La Commission de la Transparence considère que TAGRISSO (osimertinib), en traitement adjuvant, apporte une amélioration du service médical rendu mineure (ASMR IV) par rapport à la stratégie de prise en charge actuelle du CBNPC de stade IB-IIIA avec mutations activatrices de l'EGFR par délétion de l'exon 19 ou substitution de l'exon 21 (L858R) après résection tumorale complète et chimiothérapie adjuvante si indiquée.

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Pembrolizumab	Keytruda	KEYTRUDA, en association à une chimiothérapie dans le traitement des patients adultes atteints d'un cancer du sein triple négatif localement récurrent non résécable ou métastatique, dont les tumeurs expriment PD-L1 avec un CPS ≥ 10 et qui n'ont pas reçu de chimiothérapie antérieure pour la maladie métastatique.	Avis de la CT 30/05/2022	https://www.has-sante.fr/jcms/p_3338759/fr/keytruda-pembrolizumab-cancer-du-sein-triple-negatif	**Nouvelle indication.** Avis favorable au remboursement dans l'extension d'indication : KEYTRUDA, en association à une chimiothérapie dans le traitement des patients adultes atteints d'un cancer du sein triple négatif localement récurrent non résécable ou métastatique, dont les tumeurs expriment PD-L1 avec un CPS ≥ 10 et qui n'ont pas reçu de chimiothérapie antérieure pour la maladie métastatique. KEYTRUDA, en association à une chimiothérapie, apporte une amélioration du service médical rendu modérée (ASMR III) par rapport à la chimiothérapie seule dans le traitement de première ligne des patients adultes atteints d'un cancer du sein triple négatif localement récurrent non résécable ou métastatique, dont les tumeurs expriment PD-L1 avec un CPS = 10.
Roxadustat	Evrenzo	traitement de l'anémie symptomatique associée à une maladie rénale chronique uniquement chez les patients adultes qui ne sont pas déjà traités par un agent stimulant l'érythropoïèse (ASE), non dialysés ou dialysés depuis moins de 4 mois.	Avis de la CT 02/05/2022	https://www.has-sante.fr/jcms/p_3334259/fr/evrenzo-roxadustat-anemie-symptomatique	**Première évaluation.** Avis favorable au remboursement dans le traitement de l'anémie symptomatique associée à une maladie rénale chronique uniquement chez les patients adultes qui ne sont pas déjà traités par un agent stimulant l'érythropoïèse (ASE), non dialysés ou dialysés depuis moins de 4 mois. Avis défavorable au remboursement dans les autres populations de l'AMM, c'est-à dire : ●tous les patients qui reçoivent déjà un traitement par ASE, qu'ils soient dialysés ou non, ● les patients dialysés depuis au moins 4 mois qui ne sont pas déjà traités par un ASE. la Commission de la transparence considère qu'EVRENZO (roxadustat) n'apporte pas d'amélioration du service médical rendu (ASMR V) en comparaison aux agents stimulant l'érythropoïèse (ASE) dans le traitement de l'anémie symptomatique associée à une MRC chez les patients adultes non dialysés ou dialysés depuis moins de 4 mois et n'étant pas en cours de traitement par un ASE.
Sofosbuvir/ Velpatasvir	Epclusa	EPCLUSA est indiqué pour le traitement de l'infection chronique par le virus de l'hépatite C (VHC) chez les patients âgés de 3 ans et plus	Avis de la CT	https://www.has-sante.fr/upload/docs/evamed/CT-19718_EPCLUSA_PIC_INS_AvisDef_CT19718_CT19722.pdf	**Nouvelle indication.** Avis favorable au remboursement dans l'extension d'indication au traitement de l'infection chronique par le virus de l'hépatite C (VHC) chez les enfants âgés de 3 ans à moins de 6 ans. Avis favorable au remboursement des nouvelles présentations EPCLUSA (sofosbuvir/velpatasvir) 200 mg/50 mg et 150 mg/ 37,5 mg, en granulés enrobés en sachet chez les enfants à partir de 6 ans dans les mêmes conditions que les présentations déjà inscrites. EPCLUSA (sofosbuvir/velpatasvir) apporte, comme chez l'adulte, une amélioration du service médical rendu mineure (ASMR IV) dans la prise en charge de l'hépatite C chronique chez les enfants âgés de 3 ans à moins de 6 ans.

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Sofosbuvir/ Voxilaprévir/ Velpatasvir	Vosevi	Traitement de l'infection chronique par le virus de l'hépatite C (VHC) chez les patients âgés de 12 ans et plus et pesant au moins 30 kg.	Avis de la CT 17/05/2022	https://www.has-sante.fr/jcms/p_3337938/fr/vosevi-sofosbuvir/-voxilaprevir/-velpatasvir-vhc	**Nouvelle indication.** Avis favorable au remboursement dans le traitement de l'infection chronique par le virus de l'hépatite C (VHC) chez les patients âgés de 12 ans et plus et pesant au moins 30 kg. VOSEVI (sofosbuvir /velpatasvir /voxilaprévir) apporte, comme chez l'adulte, une amélioration du service médical rendu mineure (ASMR IV) dans la prise en charge de l'hépatite C chronique chez les adolescents âgés de 12 ans à moins de 18 ans.
Sotorasib	Lumykras	Traitement des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) avancé, présentant la mutation KRAS G12C, dont la maladie a progressé après au moins une ligne de traitement systémique antérieur	Avis de la CT 04/05/2022	https://www.has-sante.fr/jcms/p_3337488/fr/lumykras-sotorasib-cancer-du-poumon	**Autorisation d'accès précoce** octroyée à la spécialité LUMYKRAS (sotorasib) dans l'indication « en monothérapie dans le traitement des patients adultes atteints d'un cancer bronchique non à petites cellules (CBNPC) avancé, présentant la mutation KRAS G12C, dont la maladie a progressé après au moins une ligne de traitement systémique antérieur ».
Tofacitinib	Xeljanz	Traitement du cancer de la prostate hormono-dépendant localisé à haut risque ou localement avancé en association avec une radiothérapie. - Traitement néoadjuvant à une radiothérapie chez les patients présentant un cancer de la prostate hormono-dépendant localisé à haut risque ou localement avancé	Avis de la CT 20/05/2022	https://www.has-sante.fr/jcms/p_3337941/fr/xeljanz-tofacitinib-arthrite-juvenile-idiopathique-polyarticulaire	**Inscription (solution buvable) et nouvelle indication (comprimé).** Avis favorable au remboursement dans le traitement de l'arthrite juvénile idiopathique polyarticulaire active (polyarthrite à facteur rhumatoïde positif [RF+] ou négatif [RF-] et oligoarthrite étendue) et du rhumatisme psoriasique (RP) juvénile chez les patients âgés de 2 ans et plus, ayant présenté une réponse inadéquate à un traitement par DMARD antérieur. Le tofacitinib peut être administré en association au méthotrexate (MTX) ou en monothérapie en cas d'intolérance au MTX ou lorsque la poursuite du traitement avec le MTX est inadaptée. XELJANZ (tofacitinib) n'apporte pas d'amélioration du service médical rendu (ASMR V) dans la stratégie de prise en charge des arthrites juvéniles idiopathiques polyarticulaires (polyarthrite à facteur rhumatoïde positif [RF+] ou négatif [RF-] et oligoarthrite étendue) et du rhumatisme psoriasique (RP) juvénile chez les patients âgés de 2 ans et plus, ayant présenté une réponse inadéquate à un traitement par DMARD antérieur.

**Esclusi dal report i seguenti medicinali valuati da HAS perché si tratta di rivalutazioni, di generici, oppure di confezioni complementi di gamma: acide acétylsalicylique (ASPIRINE PROTECT); bétaméthasone (CELESTENE); cloxacilline sodique (CLOXACILLINE STRAGEN); delamanide (DELTYBA); émulsion lipidique 20%, glucose 19 %, solution d'acides aminés 10 % avec électrolytes (SMOFKABIVEN NUTRIBASE E); simoctocog alfa (NUWIQ); Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), de l'hépatite B (ADNr), poliomyélitique (inactivé) et conjugué de l'Haemophilus de type b (adsorbé) (VAXELIS).*

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Generic name	Brand name	Indication	Type of document	Link	Note
-	-	-	-	-	No new reports.

IQWiG

https://www.iqwig.de/en/home.2724.html

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Avacopan [G22-05]	Tavneos	Severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) in combination with rituximab or cyclophosphamide	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/g22-05.html		In accordance with §35a (1) Sentence 11 Social Code Book (SGB) V, the added medical benefit of orphan drugs is deemed as proven by the fact that they have been approved. On behalf of the Federal Joint Committee (G-BA), IQWiG therefore solely assesses the information on patient numbers and costs in the pharmaceutical company's dossier. After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. The resolution on the extent of added benefit is passed by the G-BA after the hearing. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA Website.
Burosumab [A22-12]	Crysvita	Patients with X-linked hypophosphataemia (XLH) aged 18 years and older	Dossier assessment 02/05/2022	https://www.iqwig.de/en/projects/a22-12.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

IQWiG

https://www.iqwig.de/en/home.2724.html

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Burosumab [A22-11]	Crysvita	Treatment of X-linked hypophosphataemia (XLH) in patients aged 1 to 17 years with radiographic evidence of bone disease	Dossier assessment 02/05/2022	https://www.iqwig.de/en/projects/a22-11.html	●Children aged 1 to 12 years with an RSS total score ≥ 2.0: added benefit not proven. ●Children aged 1 to 12 years with an RSS total score < 2.0: added benefit not proven. ● Adolescents aged 13 to 17 years: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Calcifediol [A22-09]	Rayaldee	Treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease Stage 3 or 4 and vitamin D insufficiency or deficiency	Dossier assessment 02/05/2022	https://www.iqwig.de/en/projects/a22-09.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Duvelisib [A22-13]	Copiktra	Adult patients with relapsed or refractory chronic lymphocytic leukaemia (CLL) after at least 2 prior therapies	Dossier assessment 02/05/2022	https://www.iqwig.de/en/projects/a22-13.html	●Patients who have not yet received a BTK inhibitor and/or a BCL-2 inhibitor: added benefit not proven. ●Patients after prior therapy with at least one BTK inhibitor: added benefit not proven. ●Patients after prior therapy with at least one BCL-2 inhibitor: added benefit not proven. ●Patients after prior therapy with at least one BTK inhibitor and one BCL-2 inhibitor: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

IQWiG

https://www.iqwig.de/en/home.2724.html

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Duvelisib [A22-14]	Copiktra	Adult patients with follicular lymphoma that is refractory to at least 2 prior systemic therapies	Dossier assessment 02/05/2022	https://www.iqwig.de/en/projects/a22-14.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Ertugliflozin [A21-158] [G22-12]	Steglatro	Inadequately controlled type 2 diabetes mellitus, as an adjunct to diet and exercise: monotherapy if metformin is unsuitable due to intolerance of contraindications; in addition to other drugs for the treatment of diabetes.	Dossier assessment 19/05/2022	https://www.iqwig.de/en/projects/a21-158.html	●Insulin-naive adults with type 2 diabetes mellitus with manifest cardiovascular disease who have not achieved sufficient glycaemic control with their ongoing drug treatment consisting of at least 2 blood-glucose lowering drugs in addition to diet and exercise and for whom insulin therapy is indicated: added benefit not proven ●Insulin-experienced adults with type 2 diabetes mellitus without manifest cardiovascular disease who have not achieved sufficient glycaemic control with their ongoing insulin regimen in addition to diet and exercise: added benefit not proven ●Insulin-experienced adults with type 2 diabetes mellitus with manifest cardiovascular disease who have not achieved sufficient glycaemic control with their ongoing insulin regimen: added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

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https://www.iqwig.de/en/home.2724.html

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Filgotinib [A21-155]	Jyseleca	Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or are intolerant to either conventional treatment or a biologic drug	Dossier assessment 20/05/2022	https://www.iqwig.de/en/projects/a21-155.html	●Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or have intolerance or contraindications to conventional treatment or to treatment with a biologic drug (TNFα antagonist or integrin inhibitor or interleukin inhibitor): added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Isoflurane [A22-10]	Forane	Sedation of mechanically ventilated adult patients in intensive care	Dossier assessment 02/05/2022	https://www.iqwig.de/en/projects/a22-10.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-15]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are heterozygous for the F508del mutation in the CFTR gene and have an MF mutation on the second allele	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-15.html	Hint of considerable added benefit	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-16]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are homozygous for the F508del mutation in the CFTR gene	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-16.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

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Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-17]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are heterozygous for the F508del mutation in the CFTR gene and have a gating mutation (including R117H) on the second allele	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-17.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-18]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are heterozygous for the F508del mutation in the CFTR gene and have an RF mutation on the second allele	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-18.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-19]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are heterozygous for the F508del mutation in the CFTR gene and have a mutation on the second allele that is not an MF, gating (including R117H) or RF mutation or in whom the mutation on the second allele is unknown	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-19.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

https://www.iqwig.de/en/home.2724.html

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-22]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are homozygous for the F508del mutation in the CFTR gene	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-22.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-23]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are heterozygous for the F508del mutation in the CFTR gene and have a gating mutation (including R117H) on the second allele	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-23.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-24]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are heterozygous for the F508del mutation in the CFTR gene and have an RF mutation on the second allele	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-24.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

https://www.iqwig.de/en/home.2724.html

Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Ivacaftor + [ivacaftor + tezacaftor + elexacaftor] [A22-25]	Kalydeco + [Kaftrio]	Patients with cystic fibrosis from 6 to 11 years of age who are heterozygous for the F508del mutation in the CFTR gene and have a mutation on the second allele that is not an MF, gating (including R117H) or RF mutation or in whom the mutation on the second allele is unknown	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-25.html	Added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Mepolizumab [A21-150] [A22-42]	Nucala	Add-on therapy for adults with severe chronic rhinosinusitis with nasal polyps that cannot be adequately controlled with systemic corticosteroids and/or surgery	Dossier assessment + Addendum 20/05/2022	https://www.iqwig.de/en/projects/a21-150.html	Hint of non-quantifiable added benefit	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Mepolizumab [A22-43] [A21-151]	Nucala	Add-on therapy for patients from 6 years and above with relapsing remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA)	Dossier assessment + Addendum 20/05/2022	https://www.iqwig.de/en/projects/a21-151.html	Hint of non-quantifiable added benefit	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

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Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Mepolizumab [A22-45] [A21-152]	Nucala	Add-on therapy for adult patients with inadequately controlled hypereosinophilic syndrome (HES) without an identifiable non-haematological secondary cause	Dossier assessment + Addendum 20/05/2022	https://www.iqwig.de/en/projects/a22-45.html	After addendum: Hint of major added benefit	If the need for additional work on a project commissioned by the G-BA arises during consultations, then IQWiG presents a report in the form of an "addendum". The G-BA subsequently decides on the extent of the added benefit, thus completing the early benefit assessment.
Nivolumab [A21-146] [A21-44]	Opdivo	First-line treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic gastric (stomach), gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express Programmed Cell Death-Ligand 1 (PD-L1, Combined Positive Score [CPS] ≥ 5)	Dossier assessment + Addendum 19/05/2022	https://www.iqwig.de/en/projects/a21-146.html	• Adenocarcinoma of the oesophagus: added benefit not proven. • Adenocarcinoma of the stomach or of the gastro-oesophageal junction: hint of non-quantifiable added benefit.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Nivolumab [A21-146] [A22-44]	Opdivo	First-line treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express programmed cell death ligand 1 (PD-L1, combined positive score [CPS] ≥ 5)	Dossier assessment + Addendum 20/05/2022	https://www.iqwig.de/en/projects/a22-44.html	After addendum: •Oesophageal adenocarcinoma: hint of considerable added benefit. •Gastric or gastro-oesophageal junction adenocarcinoma: hint of considerable added benefit.	If the need for additional work on a project commissioned by the G-BA arises during consultations, then IQWiG presents a report in the form of an "addendum". The G-BA subsequently decides on the extent of the added benefit, thus completing the early benefit assessment.

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Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Ozanimod [A21-166]	Zeposia	Adults with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or are intolerant to either conventional treatment or a biologic drug	Dossier assessment 20/05/2022	https://www.iqwig.de/en/projects/a21-166.html	• Patients who have had an inadequate response with, lost response to, or have intolerance or contraindications to conventional treatment: added benefit not proven • Patients who have had an inadequate response with, lost response to, or are intolerant to treatment with a biologic drug (TNFα antagonist or integrin inhibitor or interleukin inhibitor): added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Pembrolizumab [A21-144] [A22-37]	Keytruda	First-line treatment of locally advanced unresectable or metastatic carcinoma of the oesophagus or human epidermal growth factor receptor 2 (HER2)-negative gastroesophageal junction adenocarcinoma in adults whose tumours express programmed cell death ligand 1 (PD-L1) (combined positive score [CPS] ≥ 10)	Dossier assessment + Addendum 05/05/2022	https://www.iqwig.de/en/projects/a21-144.html	• Adult patients with locally advanced or metastatic squamous cell carcinoma of the oesophagus that cannot be treated curatively and whose tumours express PD-L1 (CPS ≥ 10); first-line treatment: hint of major added benefit •Adult patients with locally advanced or metastatic HER2-negative adenocarcinoma of the oesophagus or of the gastroesophageal junction that cannot be treated curatively and whose tumours express PD-L1 (CPS ≥ 10); first-line treatment: added benefit not proven •Adult patients with locally advanced or metastatic HER2-positive adenocarcinoma of the oesophagus that cannot be treated curatively and whose tumours express PD-L1 (CPS ≥ 10); first-line treatment: added benefit not proven	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

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Generic name	Brand name	Indication	Type of document	Link	Recommendation	Note
Pembrolizumab [A21-145] [A22-36]	Keytruda	Adult patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumours express PD-L1 (combined positive score ≥ 10) and who have not received prior chemotherapy for metastatic disease	Dossier assessment + Addendum 05/05/2022	https://www.iqwig.de/en/projects/a21-145.html	Hint of non-quantifiable added benefit	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Sacituzumab [A21-154] [A22-41]	Trodelvy	Adult patients with unresectable or metastatic triple-negative breast cancer who have had two or more prior systemic therapies including at least one of them for advanced disease	Dossier assessment + Addendum 20/05/2022	https://www.iqwig.de/en/projects/a21-154.html	Hint of major added benefit	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Sofosbuvir/velpatasvir [A22-26]	Epclusa	Children from 3 to < 6 years of age with chronic HCV infection	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-26.html	● Genotype 1, 4, 5 or 6: added benefit not proven. ●Genotype 2 or 3: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.
Sotorasib [A22-28]	Lumykras	Adult patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation and who have progressed after at least one prior line of systemic therapy	Dossier assessment 16/05/2022	https://www.iqwig.de/en/projects/a22-28.html	●After first-line therapy with a PD-1/PD-L1 antibody as monotherapy: added benefit not proven. ●After first-line therapy with cytotoxic chemotherapy: added benefit not proven. ●After first-line therapy with a PD-1/PD-L1 antibody in combination with platinum-containing chemotherapy or after sequential therapy with a PD-1/PD-L1 antibody and platinum-containing chemotherapy: added benefit not proven.	After completion of the assessment by IQWiG the Federal Joint Committee (G-BA) conducts a commenting procedure. This may provide supplementary information and as a result lead to a modified benefit assessment. Further information and the decision on the early benefit assessment can be found on the relevant page of the G-BA website.

NICE National Institute for Health and Care Excellence

https://www.nice.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Recommendation
Avelumab	Bavencio	maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy	Technology appraisal guidance [TA788] 11/05/2022	https://www.nice.org.uk/guidance/ta788/resources/avelumab-for-maintenance-treatment-of-locally-advanced-or-metastatic-urothelial-cancer-after-platinumbased-chemotherapy-pdf-82611563554501	Avelumab is recommended as an option for maintenance treatment of locally advanced or metastatic urothelial cancer that has not progressed after platinum-based chemotherapy in adults, only if: • avelumab is stopped at 5 years of uninterrupted treatment or earlier if the disease progresses and • the company provides avelumab according to the commercial arrangement. The list price is £768.00 per 200 mg/10 ml concentrate for solution for infusion vials (excluding VAT; BNF online, accessed February 2022). Avelumab meets NICE's criteria to be considered a life-extending treatment at the end of life. This is because although there are different ways to estimate life expectancy, overall, it is likely that most people who would have been eligible for treatment with avelumab would live on average less than 24 months. The most likely cost-effectiveness estimates are within what NICE usually considers an acceptable use of NHS resources for end of life treatments. So avelumab is recommended, if it is stopped at 5 years or earlier if the disease progreses.
Romosozumab	Evenity	severe osteoporosis	Technology appraisal guidance [TA791] 25/05/2022	https://www.nice.org.uk/guidance/ta791/resources/romosozumab-for-treating-severe-osteoporosis-pdf-82611612263365	Romosozumab is recommended as an option for treating severe osteoporosis in people after menopause who are at high risk of fracture, only if: • they have had a major osteoporotic fracture (spine, hip, forearm or humerus fracture) within 24 months (so are at imminent risk of another fracture) and • the company provides romosozumab according to the commercial arrangement. The price for romosozumab is £427.75 for 2 pre-filled pens administered subcutaneously as a single monthly dose (BNF online, accessed October 2021). The company has a commercial arrangement. This makes romosozumab available to the NHS with a discount. Clinical trial evidence suggests that romosozumab followed by alendronic acid is more effective at reducing the risk of fractures than alendronic acid alone. Comparing romosozumab indirectly with other bisphosphonates and other medicines for this condition suggests that romosozumab is likely to be at least as effective at reducing the risk of fractures in people with osteoporosis after menopause. But the extent of the benefit is uncertain because of differences between the trial populations in the indirect comparisons. The most likely cost-effectiveness estimates for romosozumab followed by alendronic acid, compared with alendronic acid alone, are within what NICE normally considers an acceptable use of NHS resources. So, romosozumab is recommended

NICE National Institute for Health and Care Excellence

https://www.nice.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Recommendation
Tepotinib	Tepmetko	advanced non-small-cell lung cancer with MET gene alterations	Technology appraisal guidance [TA789] 18/05/2022	https://www.nice.org.uk/guidance/ta789/resources/tepotinib-for-treating-advanced-nonsmallcell-lung-cancer-with-met-gene-alterations-pdf-82611565234117	Tepotinib is recommended, within its marketing authorisation, as an option for treating advanced non-small-cell lung cancer (NSCLC) with METex14 skipping alterations in adults, only if the company provides tepotinib according to the commercial arrangement. The list price of tepotinib is £7,200 for 60×250-mg tablets. The company has a commercial arrangement. This makes tepotinib available to the NHS with a discount. Clinical trial evidence suggests a clinical benefit for tepotinib. It has been indirectly compared with other treatments in 2 ways, but the results of both are uncertain. Tepotinib meets NICE's criteria to be considered a life-extending drug at the end of life for people who have had previous treatment, but not for people who have not had previous treatment. For both groups, the cost-effectiveness estimates are within the range NICE normally considers an acceptable use of NHS resources. So, tepotinib is recommended.

Scottish Medicines Consortium

https://www.scottishmedicines.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Advice	Evidences
Cemiplimab	Libtayo	As monotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: locally advanced NSCLC who are not candidates for definitive chemoradiation, or metastatic NSCLC	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/cemiplimab-libtayo-nonsub-smc2489/	in the absence of a submission from the holder of the marketing authorisation: cemiplimab (Libtayo®) is not recommended for use within NHSScotland.	The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.
Dapagliflozin	Forxiga	Adult treatment of chronic kidney disease.	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/dapagliflozin-forxiga-full-smc2428/	following a full submission: dapagliflozin (Forxiga®) is accepted for restricted use within NHSScotland.	In a randomised, double-blind, phase III study in patients with chronic kidney disease, treatment with dapagliflozin added to standard of care significantly reduced the risk of first occurrence of ≥50% sustained decline in estimated glomerular filtration rate, end stage renal disease, cardiovascular death or renal death when compared with standard of care alone.
Daratumumab	Darzalex	In combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/daratumumab-iv-and-sc-darzalex-full-smc2416/	following a full submission: daratumumab (Darzalex®) is not recommended for use within NHSScotland	In an open-label, phase III study, the addition of daratumumab to bortezomib, melphalan, and prednisone was associated with a significant improvement in progression-free survival. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC.

Scottish Medicines Consortium

https://www.scottishmedicines.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Advice	Evidences
Filgotinib	Jyseleca	Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/filgotinib-jyseleca-uc-abb-smc2467/	following an abbreviated submission: filgotinib (Jyseleca®) is accepted for use within NHSScotland.	Filgotinib provides an additional treatment choice in the therapeutic class of janus kinase (JAK) inhibitors. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.
Liraglutide	Saxenda	As an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of:	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/liraglutide-saxenda-resub-smc2455/	following a resubmission: liraglutide (Saxenda®) is accepted for restricted use within NHSScotland.	In a phase III study, liraglutide, as an adjunct to diet and exercise, was associated with significant reduction in body weight compared with placebo in patients with BMI ≥30kg/m² or ≥27kg/m² if they had dyslipidaemia or hypertension. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. *a lower BMI cut-off may be more appropriate for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population.
Mepolizumab	Nucala	As an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA).	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/mepolizumab-nucala-egpa-nonsub-smc2490/	in the absence of a submission from the holder of the marketing authorisation: mepolizumab (Nucala®) is not recommended for use within NHSScotland.	The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

Scottish Medicines Consortium

https://www.scottishmedicines.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Advice	Evidences
Mepolizumab	Nucala	As add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause.	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/mepolizumab-nucala-hs-nonsub-smc2488/	in the absence of a submission from the holder of the marketing authorisation: mepolizumab (Nucala®) is not recommended for use within NHSScotland.	The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.
Mepolizumab	Nucala	As an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate control.	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/mepolizumab-nucala-scr-nonsub-smc2491/	in the absence of a submission from the holder of the marketing authorisation: mepolizumab (Nucala®) is not recommended for use within NHSScotland.	The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.
Nivolumab	Opdivo	as monotherapy for the adjuvant treatment of adult patients with completely resected oesophageal or gastro-oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy.	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/nivolumab-opdivo-full-smc2429/	following a full submission: nivolumab (Opdivo®) is accepted for use within NHSScotland.	In one randomised, double-blind, phase III study, nivolumab significantly improved disease-free survival compared with placebo in patients with oesophageal or gastro-oesophageal junction cancer who had complete resection and residual pathologic disease after neoadjuvant chemoradiotherapy. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.
Oritavancin	Tenkasi	treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/oritavancin-tenkasi-resub-smc2285/	following a resubmission: oritavancin (Tenkasi®) is accepted for restricted use within NHSScotland.	In two randomised, phase III, double-blind studies of patients with ABSSSI, oritavancin was non-inferior to a glycopeptide antibiotic for clinical cure at the end of treatment in the clinically evaluable population.

Scottish Medicines Consortium

https://www.scottishmedicines.org.uk/

Generic name	Brand name	Indication	Type of document	Link	Advice	Evidences
Pembrolizumab	Keytruda	In combination with platinum and fluoropyrimidine based chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS≥10.	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/pembrolizumab-keytruda-full-smc2420/	following a full submission assessed under the end of life medicine process: pembrolizumab (Keytruda®) is accepted for restricted use within NHSScotland.	SMC Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. In a phase III study, pembrolizumab in combination with chemotherapy was associated with significantly improved progression-free survival and overall survival compared with chemotherapy alone. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.
Venetoclax	Venclyxto	In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).	Medicine advice 9.05.2022	https://www.scottishmedicines.org.uk/medicines-advice/venetoclax-venclyxto-full-smc2427/	following a full submission: venetoclax (Venclyxto®) is accepted for restricted use within NHSScotland.	Venetoclax in combination with obinutuzumab, compared with standard therapies, was associated with clinical benefits in patients who were fit and unfit to receive FCR chemo-immunotherapy. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.